# Xbrane Biopharma Year-end Report 2022



"EMA's approval of Ximluci® positions Xbrane as a leading Biosimilar Developer"

Martin Åmark, CEO Solna February 17<sup>th</sup>, 2023

\*) European Medicines Agency

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## Xbrane has a portfolio addressing €53 billion of peak reference product sales

Candidate	Reference Product	Indication	Patent Expiry	Peak sales estimate*	Development Phase	Next milestone	Commercialization Partner
Ximluci	LUCENTIS' RANIBIZUMAB INJECTION	<ul> <li>Age-related macular degeneration</li> <li>Diabetic macular edema,</li> <li>Diabetic related retinopathy</li> </ul>	2020/22 (US/EU)	€2.8b*	Approved	Q1:2023 Submission of BLA Q1 2023: Launch in Europe 2023: Regulatory submissions in MENA	STADA Arzneimittel  BAUSCH+LOMB
BIIB801	CIMZIO° (certolizumab pegol)	<ul><li>Rheumatoid arthritis</li><li>Psoriasis</li><li>Crohn's disease</li></ul>	2024/25 (US/EU)	€2b	Process Scale-up	2023 : Production of clinical material	Biogen
Xdivane™	<b>OPDIVO</b> . (nivolumab)	<ul> <li>Multiple oncology indications including Lung, liver, head &amp; neck, kidney, colorectal cancer</li> </ul>	2028/30 (US/EU)	€13b	Process development	2023: Contract CMO and scale up	Oncology portfolio with potential to out-license in one deal
Xtrudane™	KEYTRUDA° (pembrolizumab)	and melanoma	2029/31 (US/EU)	€26b	Cell-line development	2023 : Develop pilot scale process	
Xdarzane™	DARZALEX* (daratumumab) injection for intravenous infusion 100 mg/5 mL, 400 mg/20 mL	Multiple Myeloma	2029/31 (US/EU)	<b>€</b> 9b	Cell-line development		

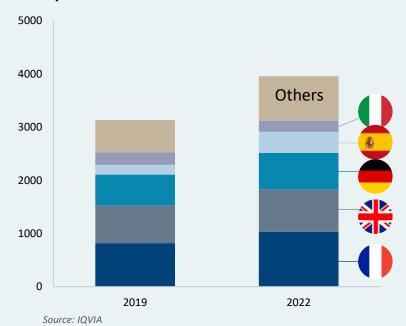
\*)Evaluate Pharma

Ambition to initiate at least one new biosimilar development program per year

#### STADA's Ximluci® launch in Europe & UK addresses a €4 billion market

#### **Europe – a €4 bn market opportunity**

#### **Europe retinal VEGF inhibitor market € million**



- → Market growth of 8% p.a. 2019-2022
- → Average price of Lucentis on €660 per unit and Eylea on €720 per unit

#### STADA well-armed for a successful launch

- Dedicated biosimilars team within STADA Global Specialty Care
- → Dedicated KAMs to target KOLs / compounders
- Dedicated ophthalmology field force for retail markets
- → Educational material for HCPs and patients
- Presence at key ophthalmology conferences and KOL engagement
- Experienced local tender teams in all countries for bidding and participation in key tenders
- Strong track record of successful commercialization of biosimilars:







#### Ximluci® overview

Equivalent to Lucentis<sup>®</sup> (dosing, administration, safety, efficacy, PK, immunogenicity)

"Ranibizumab has a robust and proven history as an effective anti VEGF"

Cost-effective option to Lucentis® and Eylea®

"STADA leverage 125 year heritage as a high-quality supplier of pharmaceutical medicines"

"Ximluci® is delivered via a European supply chain"



### **Upcoming Capital Market Days 2023**

- Redeye "Swedish Success Day" Feb 21<sup>st</sup>, 2023
- Aktiespararna March 13<sup>th</sup>, 2023
- BioStock Investor Meeting March 16<sup>th</sup>, 2023
- Kempen Capital Markets Day April, 2023
- ABG Life Science Summit May 31<sup>st</sup>, 2023



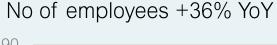
# **Aktiespararna**



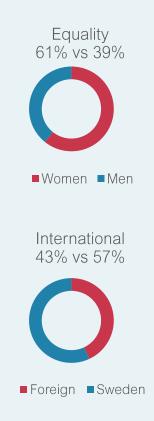


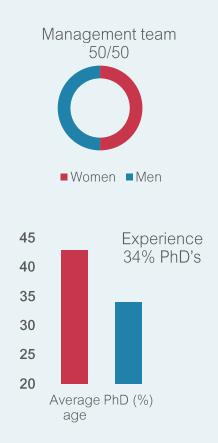
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## Company Expenses (G&A and R&D)



Total Company Expenses expensed in the P&L have increased by +35mSEK, with a number of factors contributing

- 1. Ximluci® moves from a development phase into a commercial phase, hence majority of costs do not longer justify to be capitalised.
- 2. Preparatory commercial activities for the imminent launch of Ximluci®, are accelerated.
- 3. Intensified activities cross the remaining portfolio, BIIB801, Xdivane<sup>TM</sup>, Xtrudane<sup>TM</sup> and Xdarzane<sup>TM</sup>
- 4. G&A expenditure have increased by 5mSEK mainly related to the continuing build of the company.

### Company Expenses (G&A and R&D)



Comparing "like-for-like" year-on-year, the total Operating Costs have increased by 44,8%

The total R&D costs (incl. Intangible Asset of SEK 12.9m) amount to SEK 72.4m, 86.8% of the total costs in the fourth quarter of 2022

Reclassification of the development costs for Ximluci® in accordance with IAS 38 started July 1<sup>st</sup>, 2021 now representing a lower proportion of the total spend. During the forth quarter, a total SEK 12.9m was capitalized on the Balance Sheet, somewhat higher than the two previous quarters as development activities for the prefilled syringe are accelerated.

A total of SEK 102m is now capitalized on the Balance Sheet related to Ximluci®.

#### Cash and Cash Equivalents

### Shareholders' Equity





At the end of the fourth quarter 2022, Cash amounted to 194.0 MSEK. In November, a capital raise was done bringing approx. SEK 170m before transaction costs. As previously communicated, the company has the aim to out-license the biosimilar candidates in the oncology portfolio during 2023 to split the development costs.

